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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,099	01/10/2001	Michael Laposata	M0765/7034HCL/MAT	7656

7590 03/26/2004

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Boston, MA 02210-2211

EXAMINER
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COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

09/758,099

**Applicant(s)**

LAPOSATA, MICHAEL

**Examiner**

Monique T. Cole

**Art Unit**

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-10, 19, 28, 29, 31, 35, 45, 58, 68, 78, 88 and 95-175 is/are pending in the application.
- 4a) Of the above claim(s) 1, 4-10, 19, 58, 68, 78, 88, 96-116, 140-175 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29, 31, 35, 45, 95 and 117-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II in the response dated 12/22/2003 is acknowledged. The traversal is on the ground(s) that the examination of the claims of Groups I and II would constitute an undue burden on the Examiner because the groups are classified in the same class and subclass. This is not found persuasive because though the claims may be classified in the same class and subclass, it does not negate the fact that a finding of art for one group does not necessarily read on the claims of the second group, thus requiring ancillary search and/or application of art on the part of the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28, 29, 31, 35, 45, 95 and 117-139 are rejected under 35 U.S.C. 102(b) as being anticipated by “Fatty Acid Ethyl Esters: Ethanol Metabolites Which Mediate Ethanol-Induced Organ Damage and Serve As Markers of Ethanol Intake” by Laposata (herein referred to as “Laposata”).

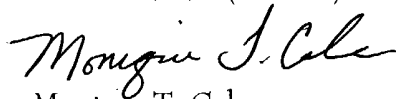
Laposata teaches that FAEE's correlate to the incidence of ethanol intake in liver and adipose tissue found in human subjects, particularly in infants and deceased individuals. FAEE's can serve as both a long term and short term marker of ethanol ingestion. FAEE's persist in the test samples for at least 24h after ethanol intake was completed. There is clinical utility for the FAEE measurement, as several algorithms have been developed to monitor ethanol intake. See page 308, 1<sup>st</sup> full paragraph; page 313, last full paragraph; page 314, 3<sup>rd</sup> full paragraph-conclusion of the reference. While the applied reference does not expressly disclose the amount of FAEE that is present in order to make the determination of ethanol intake, because such a determination is made therein, it is the Examiner's position that the amount would be within the range instantly claimed and is therefore inherent in the reference, absent any evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Monique T. Cole

Examiner

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MC